9/14/95

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

pc 128850

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Glufosinate-ammonium in/on Tree Nut Group; Fat, Meat & Mbyp of cattle, goats, horses, poultry and sheep; Eggs and Milk (PP# 8F3607).

FROM: Brian Steinwand BS
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head E.A. Doyle
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: J. Miller/E. Wilson, PM Team 23 W.Burnam
Registration Division (7505C)

Action Requested

Provide a dietary exposure analysis for the use of glufosinate-ammonium in/on the tree nut group (0.01 ppm), fat and meat (0.05 ppm), mbyp (0.10 ppm), eggs (0.05 ppm) and milk (0.02 ppm).

Discussion

Time limited tolerances already exist for the tree-nut group, except almonds. Thus, for the purposes of this analysis, almonds were added separately as a new commodity.

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.02 mg/kg bwt/day, based on a NOEL of 2.1 mg/kg bwt/day from a two-year rat chronic toxicity study with an uncertainty factor of 100 that demonstrated increased absolute and relative kidney weights in males as an endpoint effect (See memo, G. Ghali, 5/13/92). The RfD has been reviewed by the HED RfD committee (6/24/93).

Currently, a data gap exists for the rat carcinogenicity study (G. Ghali memo, 9/14/93).

Residue Information

Tolerances for glufosinate-ammonium are published in 40 CFR §180.473. Tolerance level residues and 100 percent crop treated assumptions were made for the proposed commodities.

Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2 and 3.

Chronic Exposure Analysis

Exposure from Existing Tolerances for glufosinate-ammonium:

Subgroup	Exposure (mg/kg/day)	%RfD
U.S. Population	0.000126	.627
Non-Nursing Infants (< 1)	0.000743	3.7

Proposed new Tolerances on the proposed commodities:

U.S. Population	0.000345	1.7
Non-Nursing Infants (< 1)	0.001464	7.3

If the new tolerances on the proposed commodities are approved:

U.S. Population	0.000470	2.3
Non-Nursing Infants (< 1)	0.002206	11

Conclusions

The chronic analysis for glufosinate-ammonium is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with glufosinate-ammonium. Thus, the chronic dietary risk exposure to glufosinate-ammonium appears to be minimal for these petitions on nuts, meat, fat, mbyp, eggs and milk and does not exceed the RfD for any of the DRES subgroups.

Attachments

cc: DRES; Caswell 580I; RCAB; CBTS (J. Garbus)

TABLE 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 5801 DATE: 09/12/95 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glufosinate-ammonium Caswell #5801 CAS No. 77182-82-2 A.I. CODE: 128850 CFR No. 180.31	2yr feeding- rat NOEL= 2.1000 mg/kg 40.00 ppm LEL= 7.6000 mg/kg 140.00 ppm ONCO: Undetermined.	Increased absolute and relative kidney weights in males. Both carcinogenicity studies did not establish an MTD.	ADI UF -->100 OPP RfD= 0.020000 EPA RfD= 0.000400	Oncogenicity- rat Oncogenicity- mouse (Syn.: Ignite, HOE-38966)	EPA verified 02/18/87 WHO reviewed 1991 RfD/PR reviewed 11/08/91 EPA deferred 03/24/92 RfD/PR reviewed 06/24/93 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
01014AA	GRAPES-FRESH (EXP. 7/99)	8F3607			0.050000
01014DA	GRAPES-RAISINS (EXP. 7/99)	8F3607			0.050000
01014JA	GRAPES-JUICE (EXP. 7/99)	8F3607			0.050000
03001AA	ALMONDS	8F3607	0.100000		
03002AA	BRAZIL NUTS (EXP. 7/99)	8F3607			0.100000
03003AA	CASHEWS (EXP. 7/99)	8F3607			0.100000
03004AA	CHESTNUTS (EXP. 7/99)	8F3607			0.100000
03005AA	FILBERTS, HAZELNUTS (EXP. 7/99)	8F3607			0.100000
03006AA	HICKORY NUTS (EXP. 7/99)	8F3607			0.100000
03007AA	MACADAMIA NUTS (BUSH NUTS) (EXP. 7/99)	8F3607			0.100000
03008AA	PECANS (EXP. 7/99)	8F3607			0.100000
03009AA	WALNUTS (EXP. 7/99)	8F3607			0.100000
03010AA	BUTTER NUTS (EXP. 7/99)	8F3607			0.100000
03013AA	BEECHNUTS (EXP. 7/99)	8F3607			0.100000
04001AA	APPLES-FRESH (EXP. 7/99)	8F3607			0.050000
04001DA	APPLES-DRIED (EXP. 7/99)	8F3607			0.050000
04001JA	APPLES-JUICE (EXP. 7/99)	8F3607			0.050000
06002AA	BANANAS-UNSPECIFIED (EXP. 7/99)	2E4057			0.300000
06002AB	BANANAS-FRESH (EXP. 7/99)	2E4057			0.300000
06002DA	BANANAS-DRIED (EXP. 7/99)	2E4057			0.300000
06016AA	PLANTAINS (EXP. 7/99)	2E4057			0.300000
43058AA	WINE AND SHERRY (EXP. 7/99)	8F3607			0.050000
50000DB	MILK-NON-FAT SOLIDS	8F3607	0.020000		
50000FA	MILK-FAT SOLIDS	8F3607	0.020000		
50000SA	MILK SUGAR (LACTOSE)	8F3607	0.020000		
53001BA	BEEF-MEAT BYPRODUCTS	8F3607	0.100000		
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	8F3607	0.050000		
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	8F3607	0.050000		
53002BA	GOAT-MEAT BYPRODUCTS	8F3607	0.100000		
53002FA	GOAT(BONELESS)-FAT	8F3607	0.050000		
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	8F3607	0.050000		
53003AA	HORSE	8F3607	0.050000		
53005BA	SHEEP-MEAT BYPRODUCTS	8F3607	0.100000		
53005FA	SHEEP(BONELESS)-FAT	8F3607	0.050000		
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	8F3607	0.050000		
55008BA	TURKEY-BYPRODUCTS	8F3607	0.100000		
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	8F3607	0.050000		
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	8F3607	0.050000		
55013BA	POULTRY,OTHER-BYPRODUCTS	8F3607	0.100000		
55013MA	POULTRY,OTHER-FLESH (+SKIN,W/O BONES)	8F3607	0.050000		

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glufosinate-ammonium Caswell #580I CAS No. 77182-82-2 A.I. CODE: 128850 CFR No. 180.31	2yr feeding- rat NOEL= 2.1000 mg/kg 40.00 ppm LEL= 7.6000 mg/kg 140.00 ppm ONCO: Undetermined.	Increased absolute and relative kidney weights in males. Both carcinogenicity studies did not establish an MTD.	ADI UF -->100 OPP RfD= 0.020000 EPA RfD= 0.000400	Oncogenicity- rat Oncogenicity- mouse (Syn.: Ignite, HOE-38966)	EPA verified 02/18/87 WHO reviewed 1991 RfD/PR reviewed 11/08/91 EPA deferred 03/24/92 RfD/PR reviewed 06/24/93 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
55014AA	EGGS-WHOLE	8F3607	0.05000D		
55014AB	EGGS-WHITE ONLY	8F3607	0.050000		
55014AC	EGGS-YOLK ONLY	8F3607	0.0500D0		
55015BA	CHICKEN-BYPRODUCTS	8F3607	0.100000		
55015MA	CHICKEN-FLESH(W/O SKIN,W/O BONES)	8F3607	0.050000		
55015MB	CHICKEN-FLESH(+SKIN,W/O BONES)	8F3607	D.050000		

TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 09/12/95 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glufosinate-ammonium Caswell #580I CAS No. 77182-82-2 A.I. CODE: 128850 CFR No. 180.31	2yr feeding- rat NOEL= 2.1000 mg/kg 40.00 ppm. LEL= 7.6000 mg/kg 140.00 ppm ONCO: Undetermined.	Increased absolute and relative kidney weights in males. Both carcinogenicity studies did not establish an MTD.	ADI UF -->100 OPP RfD= 0.020000 EPA RfD= 0.000400	Oncogenicity- rat Oncogenicity- mouse (Syn.: Ignite, HOE-38966)	EPA verified 02/18/87 WHO reviewed 1991 RfD/PR reviewed 11/08/91 EPA deferred 03/24/92 RfD/PR reviewed 06/24/93 On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000125	0.000470	2.348670	1.721865		
U.S. POPULATION - SPRING SEASON	0.000112	0.000442	2.208240	1.647255		
U.S. POPULATION - SUMMER SEASON	0.000119	0.000461	2.305765	1.710435		
U.S. POPULATION - FALL SEASON	0.000136	0.000491	2.456650	1.778875		
U.S. POPULATIDN - WINTER SEASON	0.000135	0.000485	2.424465	1.751155		
NORTHEAST REGION	0.000138	0.000491	2.455955	1.764755		
NORTH CENTRAL REGION	0.000115	0.000463	2.316150	1.742265		
SOUTHERN REGION	0.000101	0.000417	2.087100	1.579715		
WESTERN REGION	0.000165	0.000541	2.705920	1.881020		
HISPANICS	0.000175	0.000614	3.071295	2.197630		
NON-HISPANIC WHITES	0.000128	0.000468	2.341345	1.700015		
NON-HISPANIC BLACKS	0.000080	0.000403	2.015860	1.614725		
NON-HISPANIC OTHERS	0.000152	0.000538	2.691485	1.929465		
NURSING INFANTS (< 1 YEAR OLD)	0.000578	0.000936	4.678105	1.787505		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000743	0.002206	11.029970	7.316965		
FEMALES (13+ YEARS, PREGNANT)	0.000075	0.000316	1.581630	1.204735		
FEMALES 13+ YEARS, NURSING	0.000107	0.000410	2.049475	1.514440		
CHILDREN (1-6 YEARS OLD)	0.000403	0.001283	6.412690	4.397400		
CHILDREN (7-12 YEARS OLD)	0.000164	0.000722	3.612175	2.794530		
MALES (13-19 YEARS OLD)	0.000080	0.000454	2.270175	1.871610		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000074	0.000365	1.823495	1.454095		
MALES (20 YEARS AND OLDER)	0.000074	0.000305	1.526285	1.158055		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000078	0.000278	1.391410	1.000625		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Glufosinate-ammonium DATE: 09/12/95
CASWELL #580I

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000126	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.627	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000345	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	1.722	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000470	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	2.349	% OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000743	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	3.713	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.001464	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	7.317	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.002206	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	11.030	% OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE

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Chemical:	**Butanoic acid, 2-amino-4-(hydroxy-methyl**
PC Code:	***128850***
HED File Code	**11000 Chemistry Reviews**
Memo Date:	***09/14/95***
File ID:	**00000000**
Accession Number:	**412-02-0011**

HED Records Reference Center
03/01/2002